FDA's Vulnerability Assessment Software tool

Quick Instruction Guide

The FDA's Vulnerability Assessment Software tool uses the CARVER + Shock methodology. The software tool is a user-friendly, interactive application developed by the Food and Drug Administration's Center for Food Safety and Applied Nutrition. The software tool assists users to conduct vulnerability assessments of food products and processes to intentional contamination and support user's efforts at mitigating contamination threats to food products.

CARVER is an acronym for the following six attributes used to evaluate the attractiveness of a target for attack:

- **C**riticality: Assesses the public health and economic impacts of an attack.
- **A**ccessibility: Ability to physically access and egress from a target undetected.
- **R**ecuperability: Ability of a system to recover from an attack.
- **V**ulnerability: Ability to accomplish a successful attack.
- **E**ffect: Amount of direct loss from an attack as measured by loss of production.
- **R**ecognizability: Ease of identifying a target.

Shock, a seventh attribute, has been added to the original six to assess the combined health, economic and psychological impacts of an attack within the food industry.

The FDA's Vulnerability Assessment software tool uses all seven attributes to develop a total score for each point in the process. NOTE: Attribute scores are presented only for Criticality, Accessibility, Recuperability, and Vulnerability. The software incorporates Effect, Recognizability, and Shock attributes into the scores of the other four attributes.

During the CSVA Workshops, we will provide instruction to industry users on the functionality, capabilities, and usability of the software tool. This Train the Trainer Info Sheet provides at-a-glance helpful hints and tips to help users navigate and operate the software tool during the CSVA Workshops.
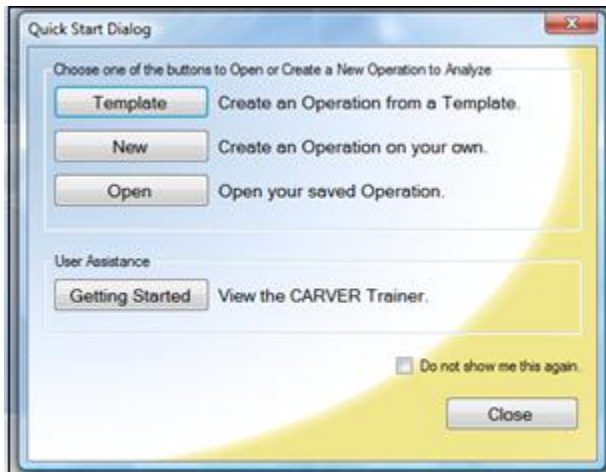
During the CSVA Workshops, we will show the users how to operate the FDA's Vulnerability Assessment software's three phases.

1. Build a Process Flow Diagram
   Choose from a template or build your own process in the interactive diagram builder.
2. Interview
   Answer questions about your process.
3. Scoring
   View your process nodes in a ranked list of CARVER attributes.

Instruction for each phase will be conducted with simultaneous translation to ensure there are no language barriers. Each user will be operating the software on his/her computer, while referring to the BMI team's computer which is projected to the group. The CSVA Workshop will incorporate guided "follow-along" instruction of the software, as well as time for users to operate the software and explore its operation individually and ask specific one-on-one questions to the BMI team and the Thai Partners.
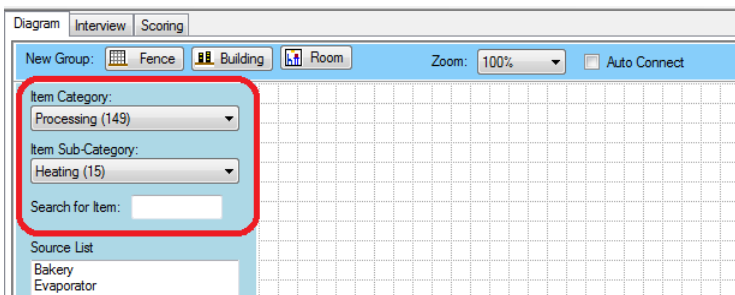
Getting Started

- The software opens when the user clicks the appropriate icon on the computer desktop

- The welcome screen provides the user with options for either starting a new assessment (using either a template flow diagram or building a new diagram), opening an existing assessment file, or launching the CARVER+Shock software trainer
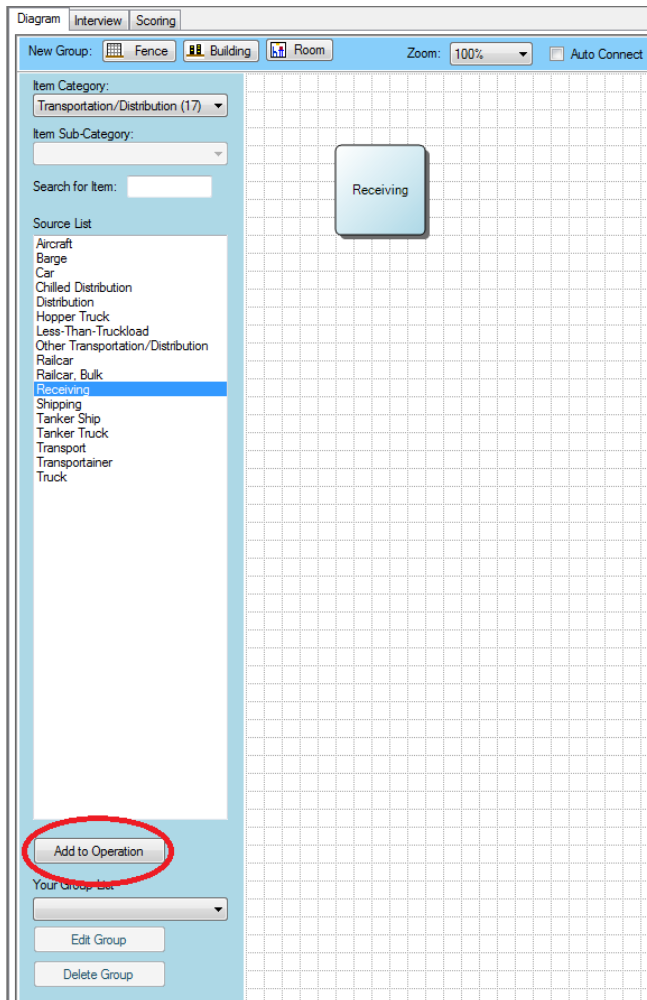

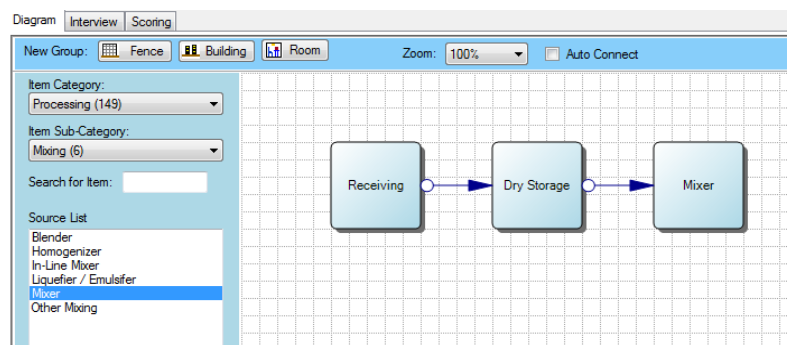## Build a Process Flow Diagram

- The process flow diagram can be created in either the chart view method or the list view method.

- The chart view method relies on the user selecting the correct node from the node selection drop down lists and adding nodes to the operation. Nodes can be found within category groupings. Some node categories also have subcategory groupings. Nodes can also be searched for using the "Search for Item" box.
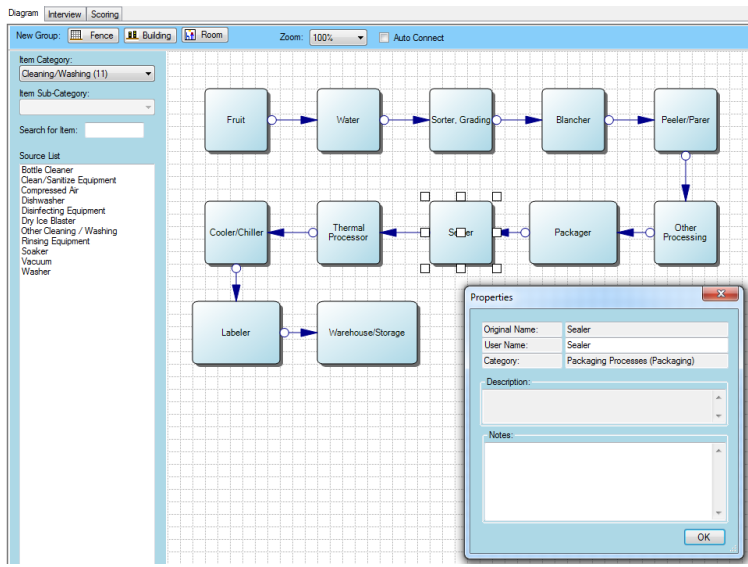
- To add a selected node to the process flow diagram, click the "Add to Operation" button and the selected node will show up in the white chart area. The new node can now be moved around and placed in the appropriate place in the process flow diagram.
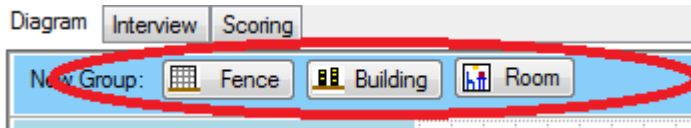

- Once nodes have been added to the white chart area, they must be connected in order to show their relationship to other nodes and how product moves through the system. To add connections, select a node and then click and hold the left mouse button as you drag to the next node. The arrow will appear as you connect nodes together.
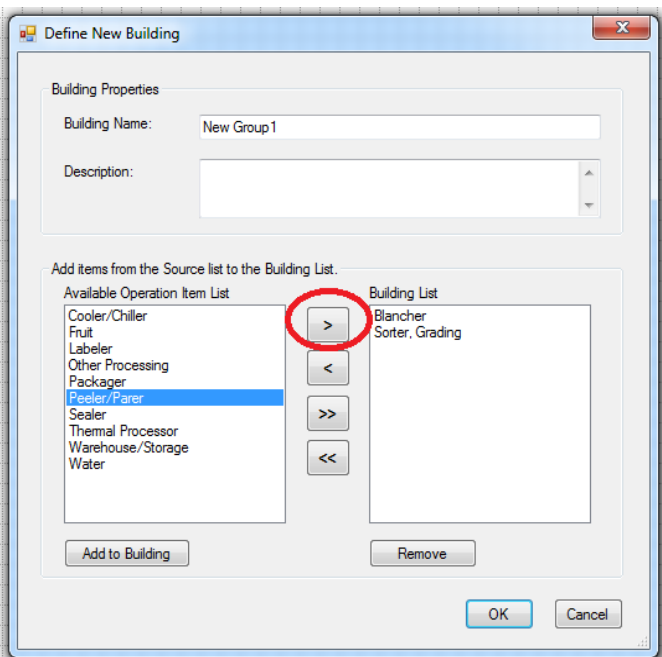
- Nodes can also be renamed as needed and notes and descriptions can be added. In order to access a node's properties and change its name or add nodes double click on the node and the Properties box will open.
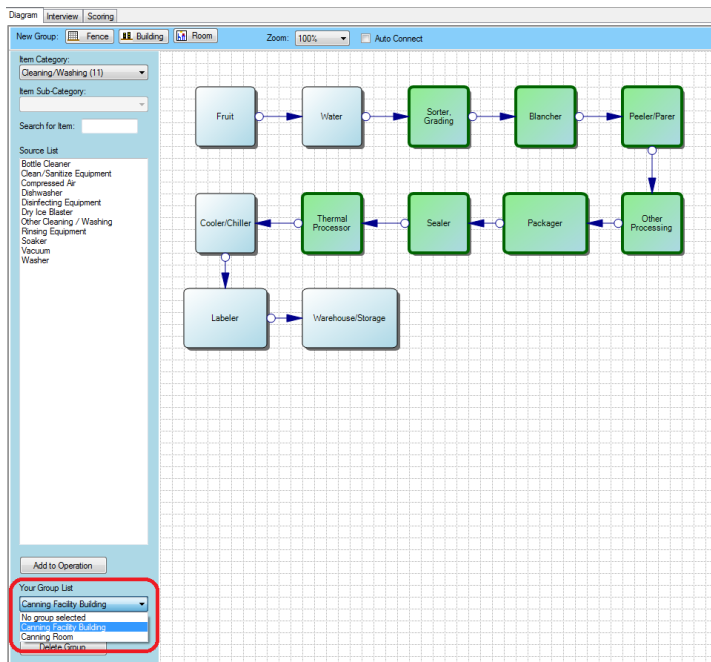

- Nodes which exist in the same room, building, or perimeter area can be placed into groups so that the software asks the most appropriate questions regarding access to that area.
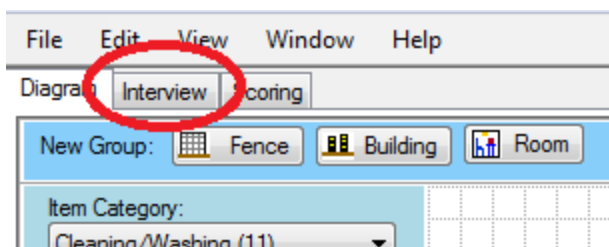

- When the appropriate group button is clicked, the Define New Fence, Building, or Room box opens. In this box, the group can be named and descriptive information added. To add nodes to the group's list, select the node from the "Available Operation Item List" and click the right arrow button to move nodes into the group.

- Member nodes of the group will be highlighted when the group is selected from the "Your Group List" at the bottom left of the screen.
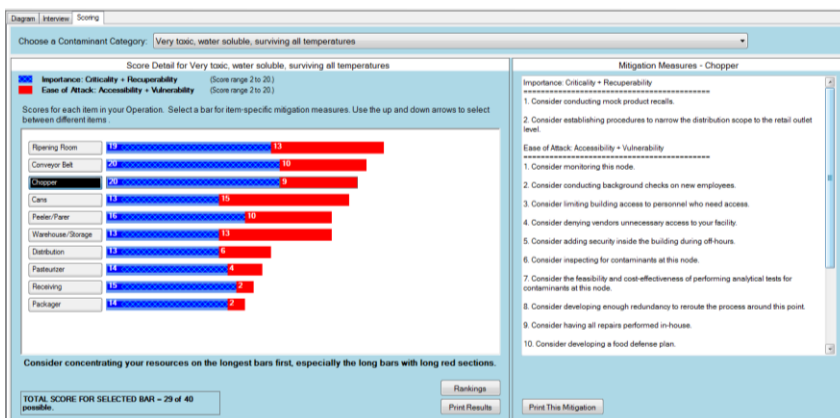

  - A node can be in more than one group or is not required to be a part of any group.
- Once all Nodes are connected and grouped as desired, the user progresses to the interview phase. Click on the Interview tab at the top left of the screen to navigate to the interview section of the software

Interview

- To progress through interview, the user must answer all the questions asked by the software about all the nodes. As the questions for nodes are completed, the color of each node in the node list at the left with change from yellow to green

- Once the user has answered all the questions, the software automatically invites the user to review the results screen.

- Review results to see where your process is most vulnerable for an intentional contamination and find a list of mitigation measures which may help reduce your risk

- The rankings, mitigation measures, and scores are all printable by using the print buttons located around the screen.

- The user can navigate to any of the 3 areas of the software by using the tabs at the top left of the screen. Diagram Interview Scoring

- The user can save the file at any time in the assessment by navigating to File>Save As and choosing a file name.